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# An evaluation of trends in the representation of patients by age, sex, and diverse race/ethnic groups in bladder and kidney cancer clinical trials

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## Abstract

**Objectives:** To determine the representation of women, minorities, and the elderly groups in clinical trials and whether participation has changed over time.

**Methods:** Retrospective study in the National Cancer Institute (NCI) Clinical Data Update System and Center for Disease Control and Prevention United States Cancer Statistics 2000 to 2019. We compared cancer incidence proportion to proportion of patients enrolled in an NCI trial when stratified by race/ethnicity, sex, and age. We performed multivariable analysis to determine the odds of participating in a clinical trial in 2015 to 2019 when compared to 2000 to 2004.

**Results:** This study included 14,094 patients, 12,169 (86.3%) non-Hispanic White patients, 662 (4.7%) Black patients, and 660 (4.7%) Hispanic patients. There were 3,701 (26.3%) female patients and 10,393 (73.7%) male patients. For bladder cancer clinical trials, Black patients and Hispanic patients were underrepresented in clinical trials compared to Non-Hispanic White patients (odds ratio [OR] 0.71, 95% confidence interval [CI] 0.57–0.88, $P = 0.002$) and (OR 0.69, 95%CI 0.54–0.88, $P = 0.003$), respectively. For kidney cancer trials, Black and Hispanic patients

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Author's contribution

Juan Javier-DesLoges, MD, MS, Writing – Conceptualization, Data curation, Formal - analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing; Ithaar Derweesh, MD - Writing – review & editing; Tyler Nelson, BS, Data curation; James Murphy, MD - Writing – review & editing; Rana R. McKay, MD - Writing – review & editing; Tyler Stewart, MD – Writing – review & editing; A. Karim Kader, MD, PhD - Writing – review & editing; Maria Elena Martinez, PhD - Writing – review & editing; Brent S. Rose, MD - Conceptualization, Project administration, Resources, Supervision.

Conflict of interest

None.

Supplementary materials

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were underrepresented in clinical trials compared to Non-Hispanic White patients (OR 0.42, OR 0.33–0.54, $P < 0.001$) and (OR 0.68, 95% CI 0.55–0.83, $P < 0.001$), respectively. Women were underrepresented in kidney cancer trials compared to men (OR 0.80, 95% CI 0.72–0.89) and similarly for bladder cancer trials (OR 0.72, 95% CI 0.64–0.81, $P < 0.001$). For bladder cancer trials, the participation of Black patients over time (OR 1.04, $P = 0.814$) and female patients over time (OR 1.03, $P = 0.741$) were unchanged. For kidney cancer trials, the participation of Black patients over time (OR 1.17, $P = 0.293$) and female patients over time (OR 1.03, $P = 0.663$) participation was also unchanged.

**Conclusion:** In this study of clinical trials in bladder and kidney cancer, we identified that Blacks, Hispanics, and females were underrepresented. Additionally, Black and female participation was unchanged over the span of 20 years.

### Keywords

Health services research; Bladder cancer; Kidney cancer; Clinical trials

## 1. Introduction

The Revitalization Act was passed by the National Institute of Health (NIH) in 1993. The purpose of this act was to increase the participation of women and minority patients in publicly funded clinical trials [1]. In JAMA 2004, Murthy et al's influential work demonstrated that significant disparities still exist in breast, colorectal, lung, and prostate clinical trials and do not adequately represent cancer incidence [2]. Since then National Cancer Institute (NCI) has placed considerable effort to mediate these disparities and created initiatives.

In our recent work, we identified that some disparities have improved over time, particularly for Black and Hispanic prostate cancer patients who were more likely to participate in a clinical trial in recent years [3]. However, outside of the 4 major cancers in the United States., there has been scant literature thus far into enrollment trends in other genitourinary malignancies, such as kidney and bladder cancer. The purpose of this study was to evaluate trends in age, sex, and race/ethnic groups in clinical trial enrollment between 2000 and 2019 for other genitourinary cancer trials sponsored by an NCI Clinical Trial Cooperative Group.

## 2. Methods

### 2.1. Data collection

In this study we followed the STROBE guidelines for reporting observational cohort studies [4]. The investigators filed a data request with the Freedom of Information Office of the NCI [5]. Through this request, data for all therapeutic NCI-sponsored clinical trials with bladder or kidney as the lead disease were acquired from 2000 to 2019. This data is populated from the NCI Clinical Data Update System, which is a database that contains enrollment information about clinical trial participants [6]. Due to limitations of the database, therapeutic modality (surgery, chemotherapy, etc.) could not be identified. Additionally factors such as socioeconomic status, insurance, geographic area, cancer stage

including localized vs. metastatic disease variables, randomization, number of arms were not available.

The investigators requested cancer incidence data (2000–2017) from by the Centers for Disease Control and Prevention (CDC) who manages the United States Cancer Statistics [7]. The United States Cancer Statistics combine the NCI's Surveillance, Epidemiology, and End Results (SEER) Program [8] with the CDC's National Program of Cancer Registries (NPCR) [9]. This database is projected to cover 100% of the United States population for incidence cancer cases [9,10]. The study was determined to be exempt by the institutional review board in coordination with the ethics committee at UC San Diego. Informed consent was waived as and the database was deidentified.

### 2.2. Study participants

We included all patients over the age of 18 who participated in a bladder or kidney cancer trial. Of note our group requested data on testicular cancer, however due to low number of patients (<100) this data was not analyzed. Designation of race and ethnicity was coded in the database, we created 5 mutually exclusive groups, Non-Hispanic White, Non-Hispanic Black (Black), Non-Hispanic Asian/Pacific Islander (Asian/Pacific Islander), Non-Hispanic American Indian/Alaska Native (American Indian/Alaska Native), Non-Hispanic Other/Unknown (Other), and any race Hispanic (Hispanic) [2]. For age, we stratified patients as elderly, older than 65 and non-elderly, younger than 65 as described in Duma et al. [11]. Lastly, for sex, patients were listed as male or female. Patients with missing data were excluded from the study, in total we excluded 143 patients from the initial cohort, which is rate of 1.0%.

### 2.3. Statistical analysis

We determined the representation of each subgroup by calculating an enrollment fraction, previously described by Murthy et al. [2]. Enrollment Fraction is defined as the number of patients enrolled in a trial over the total cancer incidence in the corresponding years. For example, 10 patients enrolled in a clinical trial / 10,000 patients with bladder cancer would yield an Enrollment Fraction of 0.10%. Thus, we analyzed the representation of racial/ethnic, age, and sex groups in the year 2015 to 2019 and performed Pearson's $\chi^2$ of independence. Lastly, we calculated crude odds ratios for each subgroup. Non-Hispanic White was used as the referent for race/ethnicity, patients younger than 65 were used as the referent for age, and patients who were male were used as the referent for the analysis involving sex. For instance, if the odds ratio of participation in a clinical trial is 0.5 for Hispanic patients with bladder cancer, this would indicate that the odds of a Hispanic patient participating in a clinical trial would be 50% less likely compared to a Non-Hispanic White patient.

In our secondary analysis, we performed multivariable logistic regression analysis to determine odds of participating in a clinical trial for 2015 to 2019 when compared to 2000 to 2004. Our model was adjusted for race/ethnicity, age, and sex.

The statistical analysis was performed using IBMSPSS Version 27 and R version 3.6.1.

## 3. Results

The final cohort of patients included 14,094 patients, which included 12,169 (86.3%) non-Hispanic White patients, 662 (4.7%) Black patients, 660 (4.7%), Hispanic patients, 312 (2.2%) Asian/Pacific Islander patients, 61 (0.4%) American Indian/Alaska Native patients, and 230 (1.6%) other (Table 1). Patients were overall younger than 65 years, (56.1%), predominantly male (73.7%), and non-Hispanic white (86.3%) (Table 1). In Fig. 1A and B, the proportion of patients who were male and female are presented in 5-year intervals. In Fig. 1C and D, the proportion of patients who were Hispanic, Black and Asian are presented in 5 year intervals.

We evaluated clinical trial enrollment from 2015 to 2019 and compared it to the cancer incidence from 2015 to 2017 (Table 2). In our unadjusted model, for bladder cancer, both Black patients and Hispanic patients were underrepresented compared to non-Hispanic White patients, (OR 0.71, 95%CI 0.57–0.88, $P = 0.002$) and (OR 0.69, 95%CI 0.54–0.88, $P = 0.003$) respectively. Similarly, for kidney cancer, Black (OR 0.42, OR 0.33–0.54, $P < 0.001$) and Hispanic patients (OR 0.68, 95% CI 0.55–0.83, $P < 0.001$) were underrepresented compared to Non-Hispanic White patients.

When evaluating age (Table 3) we found that elderly patients were underrepresented compared to younger patients in both kidney and bladder cancer trials (OR 0.65, 95% CI 0.59–0.71, $P < 0.001$) and (OR 0.62, 95% CI 0.56–0.69, $P < 0.001$) respectively. For sex (Table 4), female patients were underrepresented compared to males in both kidney (OR 0.80, 95% CI 0.72–0.89) and bladder cancer (OR 0.72, 95% CI 0.64–0.81, $P < 0.001$).

We performed multivariable logistic regression analysis comparing the years 2000 to 2004 to 2015 to 2019 and adjusting for sex, age, and race/ethnicity (Table 5). For bladder cancer trials, Hispanic and Black patient and enrollment were unchanged (OR 1.04, $P = 0.814$) and (OR 1.45, $P = 0 = 1.04$). The participation of elderly patients increased (OR 1.80, 95%CI 1.55–2.09), and the participation of women was unchanged (OR 1.03, $P = 0.741$). For kidney cancer trials, the participation of Black patients was unchanged (OR 1.17, $P = 0.293$) and increased for Hispanic patients (OR 2.54, 95% CI 1.88–3.43, $P < 0.001$) and Asian/Pacific Islander patients (OR 2.27, 95%CI 1.34–3.83, $P = 0.002$). The participation of elderly patients increased (OR 1.20, 95%CI 1.04–1.38, $P = 0.011$), and for women was unchanged (OR 1.03, 95% CI 0.89–1.20, $P = 0.663$).

## 4. Discussion

In this study, we present clinical trial enrollment for bladder and kidney cancer patients that spans 2 decades, 149 trials, and 14,094 patients. We found that clinical trial enrollment for Black patients and women is unchanged in 20 years of clinical trials for both kidney and bladder cancer trials. We found that Hispanic participation increased for kidney cancer trials but was unchanged for bladder cancer trials. Collectively, Blacks, Hispanics, and women were still underrepresented in bladder and kidney cancer trials when compared to their incidence. Lastly, we found that elderly participation increased for both kidney and bladder

cancer trials but were still underrepresented. These findings indicate that clinical trials disproportionately represent some groups of patients and may not reflect cancer incidence.

A focus of disparity research to date has largely focused on the 4 major organ systems of breast, colorectal, lung and prostate cancer. We previously reported our findings on prostate cancer earlier this year [3]. Our major finding was that Black and Hispanic patients are underrepresented in prostate cancer clinical trials but that participation has increased since 2000. In 2017, Duma et al. evaluated 2,020 kidney cancer patients from 2003 to 2016. The authors identified that Black patients, Hispanic patients, and women were underrepresented, but there was no subanalysis by age. In our study, we evaluated 8,626 patients from 2000 to 2019 and our results mirror those of Duma et al., and additionally found that elderly patients were underrepresented. Our findings are novel indicating an increase in Hispanic participation trials over the last 5 years as well as elderly patients, but there no changes in the participation of Black patients and women. In the end, all of these groups remain underrepresented compared to their cancer incidence.

For other genitourinary malignancies, there is scarce literature on the participation of these groups in clinical trials. We identified that Hispanic patients, Black patients, women, and elderly patients are underrepresented in bladder cancer clinical trials over the 20 year span. We did identify an increase in the participation of elderly patients in bladder cancer trials recently, but no changes for Hispanic patients, Black patients, and women. Dymanus et al. recently published similar findings about the underrepresentation of women with respect to bladder cancer when evaluating clinical trial from 2014 to 2019 [10]. Our findings mirror those of Dymanus et al., and additionally indicate a lack of change in this representation since the early 2000s. Additionally, Fletcher et al. recently reported that race/ethnic minorities were underrepresented in non-BCG responsive bladder cancer trials by a cumulatively evaluation of years1998 to 2021 [12]. Our work expands upon both prior publications by identifying when evaluating year-to-year trends, there has been no increase in the participation in participation of Black patients, Hispanic patients, or women in bladder cancer clinical trials.

Our findings are concerning, as we found a significantly disproportionate representation of men compared to women in both kidney and bladder cancer trials. Gender disparities in clinical trial enrollment are well known [13]. There have been few reasons hypothesized for this including caregiver and family responsibilities that may differentially affect women, although this has not been validated [10]. Additionally, there has been little effort with recruitment strategies surrounding women for kidney and bladder cancer trials.

An additional notable finding of our study was a rise in the proportion of Asian/Pacific Islander minorities in clinical trials when compared to Non-Hispanic White patients. In our prior study, we noted the same finding amongst colorectal and lung cancer clinical trials [3]. Our study is amongst the first to identify this finding, and while the significance is unclear it illustrates that some minority participation has increased in clinical trials over time.

These findings call for further efforts are needed to increase the participation of these groups as inclusion may counter safety concerns about treatment and abate differences in survival outcomes

### 4.1. Study limitations

Our study has limitations. From 2000 to 2019, 36% of trials were industry sponsored [14]. The NCI does not collect industry only sponsored trials in their database. Second, we could account for clerical errors in the data set. Third, due to the small number of American Indian/Alaska Native patients we could speak further to the validity of these findings. Fourth, the NCI Clinical Data Update System has limited information, we did not have access to therapeutic modality (surgery, chemotherapy, etc.), factors such as socioeconomic status, insurance status, cancer stage, or trial information such as randomization, or number of arms. Lastly, we compared cancer incidence to clinical trial enrollment population, while not all patients were eligible for these trials, this should nonetheless continue to serve as a target for primary investigators.

## 5. Conclusion

In summary, our study adds to the existing literature by expanding upon clinical trial enrollment differences for kidney and bladder cancer trials over the last 20 years. We found that Black patients, Hispanic patients, women and elderly patients are underrepresented in bladder and kidney trials and there has been little change since the early 2000s.

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Access to Data statement: Dr. Rose and Dr. Javier-DesLoges had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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The Department of Defense was not involved in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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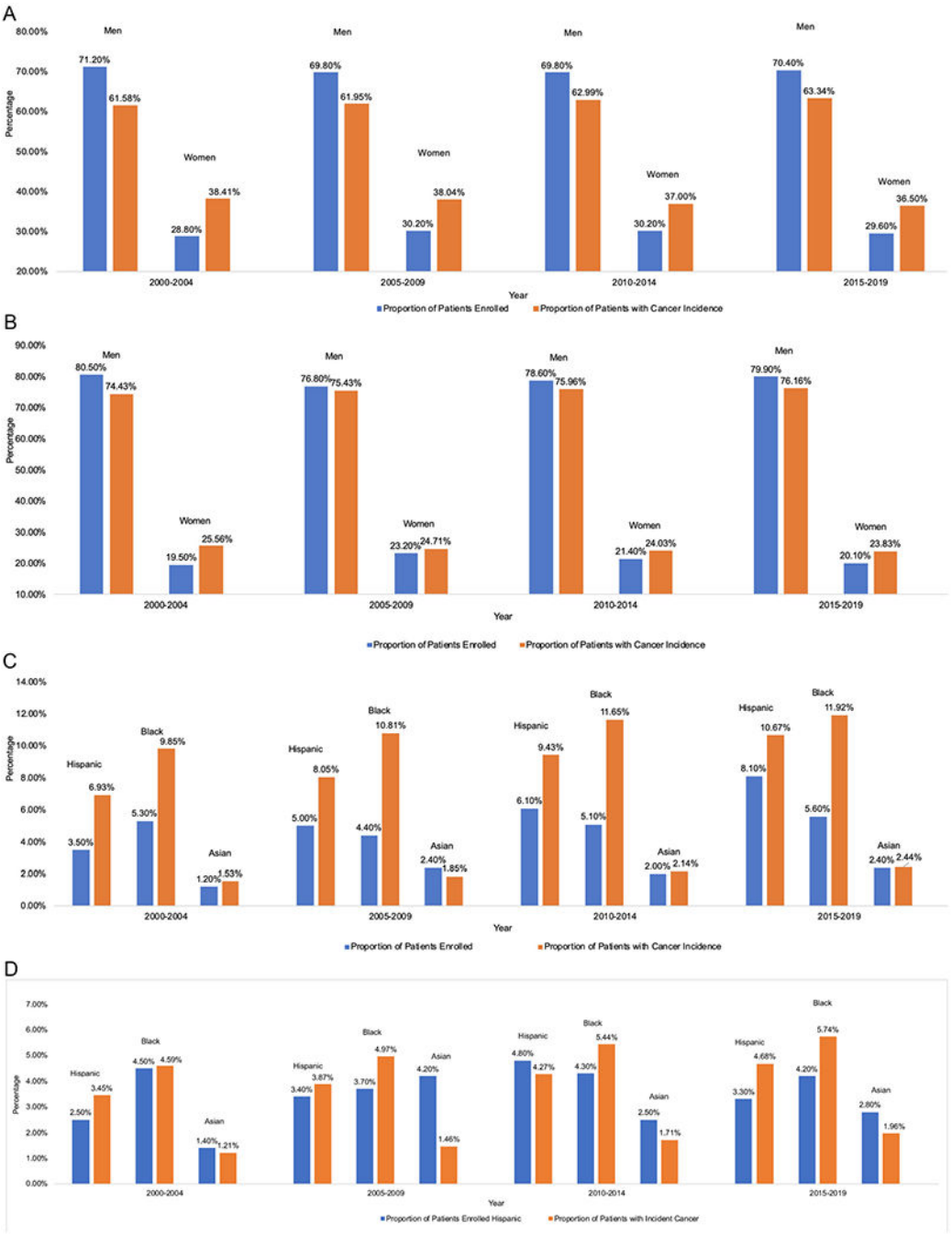


**Fig. 1.**

(A) Comparison of proportion of clinical trial enrollment vs. proportion of cancer incidence by sex for kidney cancer trials. (B) Comparison of proportion of clinical trial enrollment vs. proportion of cancer incidence by sex for bladder cancer trials. (C) Comparison of proportion of clinical trial enrollment vs. proportion of cancer Incidence by race/ethnicity for kidney cancer trials. (D) Comparison of proportion of clinical trial enrollment vs. proportion of cancer incidence by race/ethnicity for bladder cancer trials.

**Table 1**

Participants in bladder and kidney national cancer institute cooperative group trials and proportion of incidence cancer patients in the United States according to race/ethnicity, age, and sex, 2000 to 2019.

| Characteristic | Bladder and kidney cancer *n* = 14,094 | Percent incident cancer in U.S. | Bladder cancer*n* = 5,468 | Percent incident cancer in U.S. | Kidney cancer *n* = 8,626 | Percent incident cancer in U.S. |
|---|---|---|---|---|---|---|
| Race/ethnicity | No (%) | % | No (%) | % | No (%) | % |
| Non-Hispanic White | 12,169 (86.3%) | 83.25% | 4,780 (87.4%) | 88.02% | 7,389 (85.7%) | 76.84% |
| Black | 662 (4.7%) | 7.69% | 232 (4.2%) | 5.15% | 420 (5.0%) | 11.0% |
| Hispanic | 660 (4.7%) | 6.06% | 197 (3.6%) | 4.03% | 463 (5.4%) | 8.79% |
| Asian/Pacific Islander | 312 (2.2%) | 1.75% | 143 (2.6%) | 1.56% | 169 (2.0%) | 1.99% |
| American Indian/Alaska Native | 61 (0.4%) | 0.51% | 15 (0.3%) | 0.29% | 46 (0.5%) | 0.81% |
| Other | 230 (1.6%) | 0.74% | 101 (1.8%) | 0.94% | 129 (1.5%) | 0.48% |
| Age, years | | | | | | |
| <65 | 7,902 (56.1%) | 36.52% | 2,196 (40.2%) | 27.06% | 5,706 (66.1%) | 49.24% |
| >65 | 6,192 (43.9%) | 63.47% | 3,272 (59.8%) | 72.93% | 2,920 (33.9%) | 50.75% |
| Sex | | | | | | |
| Female | 3,701 (26.3%) | 30.08% | 1,134 (20.7%) | 24.56% | 2,567 (29.8%) | 37.49% |
| Male | 10,393 (73.7%) | 69.91% | 4,334 (79.3%) | 75.43% | 6,059 (70.2%) | 62.5% |

**Table 2**

Trial enrollment for minorities vs. non-hispanic white for bladder and kidney cancer trials, 2015 to 2019.

| Race/ethnicity | No. of Trial participants | Enrollment fraction[a] | Odds ratio (95% CI) | *P* value |
|---|---|---|---|---|
| | | *Bladder cancer* | | |
| Non-Hispanic White | 1,813 | 0.93% | Referent | |
| Black | 87 | 0.67% | 0.71 (0.57–0.88) | 0.002 |
| Hispanic | 69 | 0.65% | 0.69 (0.54–0.88) | 0.003 |
| Asian/Pacific Islander | 59 | 1.33% | 1.43 (1.10–1.86) | 0.006 |
| American Indian/Alaska Native | 4 | 0.45% | 0.48 (0.18–1.30) | 0.154 |
| | | *Kidney cancer* | | |
| Non-Hispanic White | 1,076 | 0.76% | Referent | |
| Black | 75 | 0.32% | 0.42 (0.33–0.54) | <0.001 |
| Hispanic | 107 | 0.52% | 0.68 (0.55–0.83) | <0.001 |
| Asian/Pacific Islander | 32 | 0.68% | 0.89 (0.62–1.27) | 0.533 |
| American Indian/Alaska Native | 7 | 0.40% | 0.52 (0.24–1.10) | 0.090 |

[a]Enrollment fraction – Defined as patients enrolled in trials/total cancer incidence for corresponding years.

**Table 3**

Trial enrollment fraction for elderly vs. nonelderly cancer for bladder and kidney cancer trials, 2015 to 2019.

| Age | No. of trial participants | Enrollment fraction[a] | Odds ratio (95% CI) | *P* value |
|---|---|---|---|---|
| | | *Bladder cancer* | | |
| <65 | 708 | 1.24% | Referent | |
| >65 | 1370 | 0.81% | 0.65 (0.59–0.71) | <0.001 |
| | | *Kidney cancer* | | |
| <65 | 805 | 0.85% | Referent | |
| >65 | 524 | 0.53% | 0.62(0.56–0.69) | <0.001 |

[a]Enrollment fraction – Defined as patients enrolled in trials/total cancer incidence for corresponding years.

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**Table 4**

Trial enrollment fraction according for sex for bladder and kidney cancer trials, 2015 to 2019.

| Sex | No. of trial participants | Enrollment fraction[a] | Odds ratio (95% CI) | *P* value |
|---|---|---|---|---|
| | | *Bladder cancer* | | |
| Male | 1660 | 0.96% | Referent | |
| Female | 418 | 0.73% | 0.80 (0.72–0.89) | <0.001 |
| *Kidney cancer* | | | | |
| Male | 935 | 0.76% | Referent | |
| Female | 394 | 0.56% | 0.72 (0.64–0.81) | <0.001 |

[a]Enrollment fraction – Defined as patients enrolled in trials/total cancer incidence for corresponding years.

**Table 5**

Multivariable logistic regression[a] for trial enrollment 2000 to 2004 vs. 2015 to 2019.

| Characteristic | Bladder | *P* value | Kidney | *P* value |
|---|---|---|---|---|
| **Race/ethnicity** | **OR (95% CI)[b]** | | **OR (95% CI)** | |
| Non-Hispanic White | Referent | | Referent | |
| Black | 1.04 (0.73–1.49) | 0.814 | 1.17(0.87–1.58) | 0.293 |
| Hispanic | 1.45(0.92–2.27) | 0.104 | 2.54(1.88–3.43) | <0.001 |
| Asian/Pacific Islander | 2.02 (1.15–3.55) | 0.013 | 2.27 (1.34–3.83) | 0.002 |
| American Indian/Alaska Native | 2.42 (0.27–21.86) | 0.429 | 1.46 (0.54–3.93) | 0.454 |
| Other | 1.58 (0.89–2.78) | 0.112 | 1.77 (1.08–2.89) | 0.023 |
| Age | | | | |
| <65 | Referent | | Referent | |
| >65 | 1.80 (1.55–2.09) | <0.001 | 1.20 (1.04–1.38) | 0.011 |
| Sex | | | | |
| Male | Referent | | Referent | |
| Female | 1.03 (0.85–1.24) | 0.741 | 1.03 (0.89–1.20) | 0.663 |

[a]Multivariable model adjusts for age, sex, and race/ethnicity.

[b]Reference time period is 2000 to 2004.